REMARKS

Claims 34-36, 38-41, 43-45, and 47-73 are pending in the present patent application.

Alleged Indefiniteness

Claims 34-36, 38-41, 43-45, and 47-73, all claims pending, stand rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite with respect to their use of the term "sequence of aza-linked ligands." Applicants respectfully request reconsideration of this rejection, because it appears to derive from a misunderstanding as to meaning of the term "aza."

The Examiner, for example, contends that the claims are indefinite because: (i) they use the term "aza," (ii) "aza" allegedly "indicates the presence of [a] –N=N- moiety," but (iii) no –N=N- moiety appears in a chemical structure for preferred compounds that is recited in the instant specification (Office Action at page 3). Applicants note, however, that the proper term to use when referring to a –N=N- moiety is "az***o***" not "az***a***." [1] Thus, the absence of a –N=N- moiety in the recited chemical structure is in no way inconsistent with Applicants' use of "aza" in the claims.

In fact, Webster's Ninth Collegiate Dictionary (1985, p. 121) defines the term "aza- as "containing a nitrogen in place of carbon and usually the bivalent group NH for the group CH_2 or a single trivalent nitrogen atom for the group CH" (copy attached as Exhibit A). This is consistent with both paragraph [0027] of the instant specification (which states that "[t]he compounds of the invention generally comprise ligands linked to a peptide backbone via an aza nitrogen"), and the chemical structure to which the Examiner refers:

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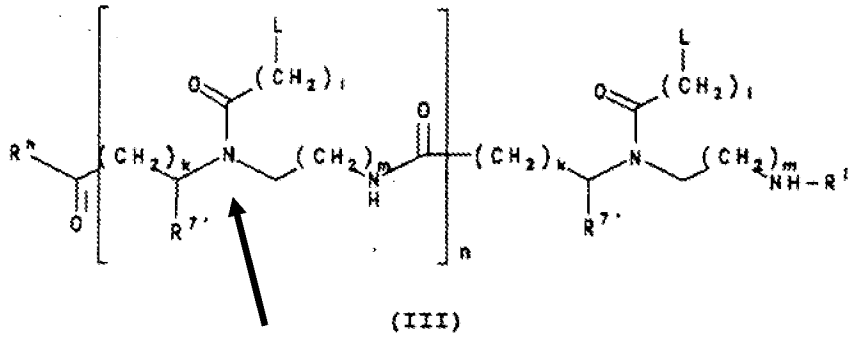
[1] For example, see e.g. the IUPAC Gold Book, defining "azo compound" as "[d]erivatives of diazene (diimide), HN=NH, wherein both hydrogens are substituted by hydrocarbyl groups, e.g. PhN=NPh azobenzene or diphenyldiazene." IUPAC. Compendium of Chemical Terminology, 2nd ed. (the "Gold Book"). Compiled by A. D. McNaught and A. Wilkinson. Blackwell Scientific Publications, Oxford (1997). XML on-line corrected version: http://goldbook.iupac.org (2006-) created by M. Nic, J. Jirat, B. Kosata; updates compiled by A. Jenkins.



(III)

Accordingly, Applicants request reconsideration and withdrawal of this rejection.

Alleged Lack of Enablement

Claims 34-36, 38-41, 43-45, and 47-73 also stand rejected under 35 U.S.C. §112, first paragraph, for alleged lack of enablement with respect to their recitation of *in vivo* extracellular administration. Applicants traverse this rejection because the Examiner has failed carry his burden by refuting the evidence of record indicating that those skilled in the art would have been able to practice the claimed methods.

An examiner seeking to reject claims for alleged lack of enablement bears a substantial burden. Indeed, claims are presumed to be enabled so long as an applicant provides a teaching of how to make and use the claimed inventions in terms which corresponds in scope to the claims. MPEP 2164.04; *In re Marzocchi*, 439 F.2d 220, 223, (CCPA 1971). This presumption is overcome only by establishing a reason to doubt the objective truth of the teaching. *Id.*

An examiner seeking to reject the instant claims faces an even heavier burden. Not only does the specification teach that the claimed compounds can be administered *in vivo* in a variety of ways to achieve a therapeutic or prophylactic effect (*see, e.g.*, paragraphs [0141]-[0147]), but Applicants have also submitted declaration testimony (in the form of an affidavit by Dr. Richard Geary) demonstrating that those skilled in the art would have been able to practice the claimed methods. The Examiner's failure to even mention the Geary declaration (much less refute it) is a telling sign that the claimed methods are enabled.

The Examiner also errs by ignoring the teaching of the Richelson patent (U.S. Patent No. 6,472,209) as it relates to enablement (Office Action at page 13). Although the Examiner appears to discount the Richelson patent because it derives from a patent application that was filed after the filing date of Applicants' priority application, the Examiner does not identify any legal or factual basis for doing so. Indeed, the Richelson patent is relevant at least because it demonstrates that the methods which Applicants describe in their priority application enable *in vivo* extracellular administration of the claimed compounds. In this respect, the patent directly refutes the Examiner's allegation that the claimed methods would not be able to achieve such modes of administration (*see, e.g.,* Office Action at page 4). The fact that Applicants' disclosure was confirmed to be enabling in a later-published document is, contrary to the Examiner's assertions, legally irrelevant. *See, e.g.*, *In re Koller*, 613 F.2d 819, 824 (C.C.P.A. 1980) (later issued patents and publications may be used to show the state of the art at the time of filing).

Because the Examiner has failed to refute the evidence of record indicating that those skilled in the art would have been able to practice the claimed methods, Applicants request that the rejection for alleged lack of enablement be reconsidered and withdrawn.

Conclusion

Applicants believe the foregoing constitutes a complete response to the Office Action and submit that all pending claims are in condition for ready allowance. An early Office Action to that effect is, therefore, earnestly solicited.

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EXHIBIT

axo·plasm \'ak-sə-ˌplaz-əm\ *n* [*axon* + *-plasm*] (ca. 1900) : the protoplasm of an axon — **axo·plas·mic** \ˌak-sə-'plaz-mik\ *adj*
ay \(ˌ)ī\ *interj* [MF *aymi* ay me] (14c) — usu. used with following *me* to express sorrow or regret
ayah \'ī-ə; 'ä-yä, -(ˌ)yä\ *n* [Hindi *āyā*, fr. Pg *aia*, fr. L *avia* grandmother] (1779) : a nurse or maid native to India
aya·hua·sca \ˌī-(y)ə-'(h)wäs-kə\ *n* [AmerSp *ayahúasca*, fr. Quechua *aya-waskha*, lit., vine of the dead] (1949) : an hallucinogenic beverage prepared from the root of a So. American vine (*Banisteriopsis caapi* of the family Malpighiaceae)
aya·tol·lah \ˌī-ə-'tō-lə, -'täl-ə, -'tōl-ə, 'ī-ə-ˌ, ˌī-ə-tə-'lä\ *n* [Per, lit., sign of God, fr. Ar *ayat* sign, miracle + *allah* God] (1979) : a religious leader among Shiite Muslims — used as a title of respect esp. for one who is not an imam
¹aye *also* **ay** \'ā\ *adv* [ME, fr. ON *ei*; akin to OE *ā* always, L *aevum* age, lifetime, Gk *aiōn* age] (13c) : ALWAYS, CONTINUALLY, EVER ⟨love that will ~ endure —W. S. Gilbert⟩
²aye *also* **ay** \'ī\ *adv* [perh. fr. ME *ye, yie* — more at YEA] (1576) : YES ⟨~, ~, sir⟩
³aye *also* **ay** \'ī\ *n, pl* **ayes** (1589) : an affirmative vote or voter ⟨the ~s have it⟩
aye–aye \'ī-ˌī\ *n* [F, fr. Malagasy *aiay*] (ca. 1781) : a nocturnal lemur (*Daubentonia madagascariensis*) of Madagascar
ayin \'ī-ən\ *n* [Heb *'ayin*, lit., eye] (1823) : the 16th letter of the Hebrew alphabet — see ALPHABET table
Ay·ma·ra \ˌī-mə-'rä\ *n, pl* **Aymara** *or* **Aymaras** [Sp *aymará*] (1860) : 1 : a member of an Indian people of Bolivia and Peru 2 **a** : the language of the Aymara people **b** : a language family of the Kechumaran stock comprising Aymara
Ayr·shire \'a(ə)r-ˌshi(ə)r, 'e(ə)r-, -shər; 'ash-ˌi(ə)r\ *n* [*Ayrshire*, Scotland] (1856) : any of a breed of hardy dairy cattle originated in Ayr and marked with blotches of red or brown with white
az- *or* **azo-** *comb form* [ISV, fr. *azote*] : containing nitrogen esp. as the bivalent group N=N ⟨azine⟩
aza- *or* **az-** *comb form* [ISV *az-* + *-a-*] : containing nitrogen in place of carbon and usu. the bivalent group NH for the group CH_2 or a single trivalent nitrogen atom for the group CH ⟨azaguanine⟩

aza- *or* **az-** *comb form* [ISV *az-* + *-a-*] : containing nitrogen in place of carbon and usu. the bivalent group NH for the group CH_2 or a single trivalent nitrogen atom for the group CH ⟨azaguanine⟩